

**REMARKS**

Claims 1-36 are pending. Claims 7, 8, 13, 14, 18-20, 27, 28, and 36 are withdrawn. Claims 1-4, 6, 9-10, 15, 23, and 32 are amended. Claim 31 is cancelled. The claim amendments are fully supported by the specification, and no new matter is being added.

**Rejection of Claims 9-12, 15-17, 21-26 and 29-35 Under 35 U.S.C. §112, First Paragraph**

The Office Action states that claims 9-12, 15-17, 21-26, and 29-35 are rejected under §112, first paragraph for allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one of skill in the art that the inventors were in possession of the claimed invention. The Office Action states that this is a new matter rejection. The Office Action states that claims 9, 10, 15, and 23 depend from claim 1, but that a method comprising the steps of claim 1 AND the steps recited in claims 9, 10, 15, and 23 does not have support in the specification. Applicants respectfully disagree and traverse the rejection.

Claim 1 recites a method comprising steps of administering a test agent to a population of transgenic insects and creating a digital image showing a trait of specimens in the population. These steps are implicit in the methods described in claims 9, 10, 15, and 23. For example, claims 9, 10, 15, and 23 each recite the generation of a phenoprofile. The specification describes that analysis of traits of test flies in response to test agents (movement traits, behavioral traits, and morphological traits) is based on the monitoring of fly movement by a recording instrument, and that the resulting images are digitized and stored in a computer-accessible manner (page 8-9). the specification describes that the step of creating a phenoprofile (a step that is recited in claims 9, 10, 15, and 23) is performed. The specification teaches at page 47, that since the traits that define phenoprofiles can be stored electronically (i.e., based on digitized images of the flies), comparison of phenoprofiles can be accomplished using computer analysis. The specification teaches further that phenoprofiles (reference and agent) can be generated and stored (in electronic form) at different times and that traits used to produce phenoprofiles can be “recalled from the recorded movies” (page 48). Accordingly, implicit in the determination of an agent or reference phenoprofile, are the steps recited in claim 1 of creating digital images showing a trait of specimens in the population, and correlating the traits with the effect of the test agent. The specification need not provide *ipsis verbis* description of the claimed invention,

provided that the specification clearly supports what is claimed. (See, e.g., *In re Alton*, 76 F.3d 1168 (Fed. Cir. 1996) (holding that “If a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if [not] every nuance of the claims is explicitly described in the specification, then adequate written description requirement is met.”); *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996) (holding that “ipsis verbis disclosure is not necessary...need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter.”)). When considered as a whole, the specification and claims as originally filed provide a description of the invention now claimed in claims 9, 10, 15, and 23, even if the specification does not expressly recite the steps of claim 1 combined with the steps of claims 9, 10, 15, and 23.

Applicants accordingly request that the rejection be reconsidered and withdrawn.

**Rejection of Claims 1-6, 9-12, 15-17, 21-26 and 29-35 Under 35 U.S.C. §112, Second Paragraph**

The Office Action states that claims 1-6, 9-12, 15-17, 21-26, and 29-35 are rejected under §112, second paragraph on various grounds. Applicants respectfully disagree and traverse the rejections.

The Office Action states that claims 1 and 2 recite “screening for the effect of a test agent on a population” and that it is not clear whether the method screens for an agent or the effect of an agent. Claims 1 and 2 have been amended to recite “determining an effect of a test agent” to clarify that the method is drawn to examining the effect that a test agent has on a population of transgenic insects.

The Office Action states that claims 1 and 2 are indefinite because while the preamble recites “screening for the effect of a test agent on a population,” the claimed method does not recite a step of screening. Claims 1 and 2 no longer recite a method of screening, but instead recite “determining the effect of a test agent” and the claims end with the step of correlating the trait of specimens with the effect of the test agent (i.e., determining the effect of the test agent).

The Office Action states that the phrase “screening for the effect of a test agent” in claims 1 and 2 lacks antecedent basis. The claims have been amended to recite “an effect.”

The Office Action states that the method steps of claims 1 and 2 are unclear because the “step of administering the test agent does not seem to relate to a step of creating an imaging showing a trait because it is not clear whether the image is created for the population after and/or before the administering the agent.” The claims have been amended to recite that the step of correlating is performed “after the administration of said agent.” The Office Action also states that the step of correlating the traits does not seem to relate to the other steps “because ‘the trait of the population’ and ‘the effect of a test agent’ are not determined in other method steps. The trait of the specimens in the population is determined from the digital image as recited in the claim, and the effect of the test agent is determined by the step of correlating. The claims are clear on their face, and are not ambiguous or indefinite.

The Office Action states that the phrase “the traits of the population” recited in claims 1 and 2 lacks proper antecedent basis. The claims have been amended to recite proper antecedent basis.

The Office Action states that claims 1 and 2 are indefinite for reciting “correlating the traits of the population with the effect of the test agents administered to the population,” and that the metes and bounds of the step comparing traits with the effect is not clear “because the criteria, algorithm, and/or specific directions for performing the comparison is not clear.” Applicants respectfully disagree. There is no requirement that the claims read like a lab notebook. That is, there is no legal requirement that the claims set out a protocol for performing a particular analytical step, when one of skill in the art, given the claims, the full description provided by the specification, and possessed of a general level of knowledge in the art, could readily determine what is being claimed. In the instant claims, there is no undisclosed algorithm or formula for associating an observed trait with the effect of a test agent, the absence of which makes the claims indefinite. One of skill in the art, having read the specification, and armed with an understanding of the scientific method would understand what is meant by “correlating the trait...with the effect of the test agent.” Correlating, means simply that the observation of a given trait is associated with the effect of the target agent, such that the target agent is identified

as producing or modifying the observed trait. The Office Action does not provide any rationale as to why one of skill in the art would find the claimed limitation to be vague or indefinite. In the event that the Examiner upholds this rejection, Applicants respectfully request that the rationale to support the rejection be set forth in a subsequent Office Action.

The Office Action also states that the limitation “correlating the traits of the population with the effect of the agents administered to the population” is indefinite because it is unclear what is correlated. Applicants respectfully disagree. The claims as originally filed and as currently amended are clear on their face as to what is being correlated in the step of correlating.

The Office Action states that claims 3-4 recite the step of determining a trait, but that “it is not clear where the step of determining fits into claims 1 or 2 from which claims 3 and 4 depend. The Office Action states that it is further unclear whether “determining” is intended to mean selecting, identifying, or altering a trait or some other step. Applicants respectfully disagree.

The claims have been amended to clarify the recited step as one of “quantifying” at least one or at least two traits, and thus the later portion of the rejection is moot. With respect to where the step of claims 3-4 “fits” into claims 1 and 2, there is no requirement that the claims specify the order of steps unless such order is essential to the operation of the claimed invention. In the present method, it is clear from the claims that the step of quantifying a trait must at least be subsequent to the step of creating a digital image showing the trait. To the extent that the examiner maintains this rejection, Applicants request that the subsequent Office Action make more clear the grounds for finding that one of skill in the art would find the claim language to be indefinite.

The Office Action also states that claims 6 and 21 are indefinite for reciting “wherein said step of determining comprises” because it lacks proper antecedent basis. Applicants have amended the claims to remedy this defect.

The Office Action states that claims 9, 10, 15, and 23 are rejected as not clear “because it is not clear whether the steps recited in claims 9, 10, 15, and 23 are intended to substitute the steps of claim 1, and if not then it is not clear where the steps fit within claim 1.” Applicants

respectfully disagree. Each of claims 9, 10, 15, and 23 simply recite further limitations of claim 1. The claims are not required to recite absolute order of the steps recited. The claims clearly indicate that the steps of claims 9, 10, 15, and 23 are additional steps to be performed in conjunction with the steps of claim 1. One of skill in the art, having read the claims in view of the specification, would understand the nature of the additional limitations recited in claims 9, 10, 15, and 23, and would further understand how to practice the method steps of claim 1 in combination with the method steps of claims 9, 10, 15, or 23.

The Office Action states that claims 9 and 10 recite a plurality of populations and are allegedly indefinite in view of the fact that claim 1 from which they depend recites “a population.” Claims 9 and 10 have been amended to depend from claim 2. Claim 2 recites a plurality of populations, and therefore claims 9 and 10 are clear and definite.

Claim 9 is rejected as indefinite for reciting “to produce.” While Applicants are not clear as to the basis on which this rejection is founded, they have nonetheless amended claim 9 to instead recite “generating a phenoprofile.” Claim 9 is clear as originally written and as currently amended.

The Office Action states that the recitation of “a reference phenoprofile” and “an agent phenoprofile” in claims 9 and 23 is indefinite because “neither the claims nor the specification specifically defines the limitations.” Applicants respectfully disagree and traverse the rejection. The specification teaches on page 10, that “the phenoprofile of a population treated with a specific test agent is referred to as the “agent phenoprofile,” and that a reference phenoprofile is “a quantitative description of the traits exhibited by a reference population. Thus, the terms are clearly defined in the specification, and the claims are clear and definite.

The Office Action states that claim 9 recites “a reference phenoprofile defined by...trait as measured in a reference population” and is unclear because it is not clear what is measured. Claim 9 has been amended to clarify this limitation, and should render the rejection moot.

The Office Action states that claims 10 and 15 recite the limitation “selecting an agent...based on the comparison” and are vague because the parameters and/or criteria for

selecting are not clear. Applicants have amended claims 10 and 15 and submit that this amendment should render the rejection moot.

The Office Action states that claim 23 is indefinite because it recites “a trait” and it is not clear whether “a trait” as recited in claim 23 is intended to be a different trait from that recited in claim 1. Applicants have amended the claims and the rejection should be moot in view of the current claim language.

In view of the foregoing, Applicants submit that the claims are clear and definite and request that the §112, second paragraph rejections be reconsidered and withdrawn.

**Rejection of Claims 1-6, 9-12, 15-17, 21-22, and 24 Under §102(b)**

The Office Action states that claims 1-6, 9-12, 15-17, 21-22, and 24 are rejected under §102(b) as allegedly anticipated by Bainton et al. The Office Action states that Bainton et al discloses a method for screening an effect of a test compound on a population of *Drosophila* flies using the methods of the currently claimed invention. Applicants respectfully disagree and traverse the rejection in view of the currently amended claims.

As amended, the instant claims are all limited to transgenic insects “comprising a human neurodegenerative disease gene.” Support for this amendment can be found in the specification at page 13 – 14. The specification teaches several human neurodegenerative disease genes and, moreover, the prior art cited by the Office Action (Chan and Bonini (2000) Cell Death and Differentiation, 7:1075) teaches a number of neurodegenerative disease genes. It is well settled that the specification need not teach that which is well known in the art (see, e.g., *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984)). Thus, the teachings in the specification combined with the state of the art at the time the instant application was filed provides ample disclosure to support the claims as amended.

Bainton et al. does not teach transgenic insects, and does not teach transgenic insects comprising a human neurodegenerative disease gene. Accordingly, Bainton et al. does not teach each limitation of the claimed invention and, thus, does not anticipate the claims.

In addition, Applicants have added new claim 37, drawn to a method for determining the effect of a test agent, wherein a phenoprint is prepared and correlated with the effect of the test agent. Support for this amendment can be found in the claims as originally filed (see, claims 20-22) and the specification at page 49-50. There is no teaching in Bainton et al. whatsoever of the generation of a phenoprint. Should the Examiner apply the current rejection to newly added claim 37, Applicants respectfully request that the Examiner indicate the specific teachings of Bainton et al. relied on for the rejection.

Applicants request that the rejection be reconsidered and withdrawn.

**Rejection of Claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35 Under §103(a)**

The Office Action states that claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35 are rejected under §103 as unpatentable over Brunner et al. in view of Hendricks et al. The Office Action states that Brunner et al. teaches a method of monitoring behavior information and screening for the effects of agents by “administering an agent, creating an image of traits, and comparing the traits with the effect of an agent.” The Office Action states that Brunner et al. teaches determining and comparing phenoprofiles, ranking agents, and selecting agents based on a comparison of test and reference phenoprofiles. The Office Action notes that Brunner et al. does not teach an insect population, but that Hendricks et al. discloses using a *Drosophila* model for studying sleep states by administering drugs to a transgenic fly and observing behavior. The Office Action concludes that it would have been obvious to modify the method of Brunner et al. to monitor the behavior of insects as taught by Hendricks et al. where the motivation is to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model. Applicants respectfully disagree and traverse the rejection.

To establish obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference

teachings (In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)). Second, there must be a reasonable expectation of success. Id. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Applicants' disclosure. Id. Finally, the prior art reference (or references when combined) **must teach or suggest all the claim limitations**. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974).

The combined disclosure of Brunner et al. and Hendricks et al. does not teach generating phenoprint, ranking or selecting test agents, or even assaying the effects of a test agent on a population. More apparent, however, is that even if combined, the teachings of Brunner et al. and Hendricks et al. do not teach the claimed method of screening for agents by digital image analysis of a transgenic insect population comprising a human neurodegenerative disease gene. As noted by the Office Action, Brunner et al. does not disclose screening an insect population. Hendricks et al. disclose *Drosophila* comprising genetic deletions in the *timeless* or *period* genes. These two genes are related to sleep and circadian rhythm in *Drosophila*, and are not associated with neurodegenerative disease, and are not human neurodegenerative disease genes.

In addition, whether taken alone or together, Brunner et al. and Hendricks et al. fail to teach the generation of a phenoprint for a transgenic fly as recited in new claim 37.

Thus, even if combined, the disclosures of Brunner et al. and Hendricks et al. fail to teach all the limitations of the claimed invention. The instant claims are, therefore, non-obvious over these references.

#### **Rejection of Claims 32-33 Under §103(a)**

The Office Action states that claims 32 and 33 are rejected as unpatentable in view of Brunner et al. in view of Hendricks et al. and in further view of Chan. The Office Action states that Brunner et al. and Hendricks et al. are applied as noted above, and make obvious the method of claims 1-6, 9-12, 15-17, 21-26, 29-31, and 34-35. The Office Action states that Brunner et al. and Hendricks et al. do not, however, teach a transgene encoding a polypeptide with an expanded polyglutamine. The Office Action states, however, that Chan discloses using transgenic *Drosophila* models for human polyglutamine disease comprising polyglutamine



repeats for elucidating mechanisms of human neurodegenerative disease. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to modify the methods of Brunner et al. and Hendricks et al. to use the *Drosophila* models taught by Chan, “where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model.” Applicants respectfully disagree and traverse the rejection. While the rejection is restricted to the polyglutamine repeat genes recited in claims 32-33, Applicants also address the rejection with respect to the human neurodegenerative disease gene limitation added to the claims by the instant amendments.

None of Brunner et al., Hendricks et al. or Chan provide the requisite motivation to make the combination suggested in the Office Action. Brunner et al. teaches a method for monitoring the behavior of animals using video imaging. There is no teaching or even suggestion in Brunner et al. to apply the behavior monitoring method to a population of insects comprising a human neurodegenerative disease gene. In fact, Brunner et al. teaches that a mouse, not a fly or insect, is “an ideal test animal” for the Brunner’s behavior monitoring system. Hendricks et al. merely teaches transgenic *Drosophila* that have mutations in the *timeless* or *period* genes, two genes involved in sleep and circadian rhythm and not even remotely associated with human neurodegenerative disease. The Chan reference is a review article that summarizes studies performed on various transgenic *Drosophila*. There is no teaching or suggestion in Chan to utilize transgenic *Drosophila* in concert with digital image analysis. The teachings of Chan are limited to genetic or molecular biological analysis of transgenic flies, and nowhere mentions monitoring behavior or movement. There is no motivation in Brunner et al. (teaching that mice are the ideal test subject) or Hendricks et al. (not remotely concerned with human neurodegenerative disease) to combine their teachings with each other, or with Chan.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). Upon reading Brunner et al., one of skill in the art may have been motivated to utilize the disclosed behavior analysis on mice, but would not have been motivated to extrapolate the teachings of Brunner et al. to an entirely different type of

organism, both genetically and behaviorally distant and distinct from mice. In addition, one of skill in the art would not have been motivated, upon reading the sleep studies of Hendricks et al., to extrapolate those teachings (focused on sleep) to the entirely different focus of study taught by Chan (focused on neurodegeneration). Upon reading the teachings of Chan, one of skill in the art would not have been motivated to completely modify the teachings of Chan, which utilized genetic and molecular biology analysis, to study flies by digital image analysis of behavior and movement. Lastly, upon reading Chan and/or Hendricks et al., one of skill in the art would not have been motivated to apply those teachings to the methods of Brunner et al., which are taught to be ideal for the analysis of mice.

At best, the combination suggested by the Office Action would be obvious to try. The Federal Circuit has long held that “obvious to try” does not constitute “obviousness.” The court in *In re O’Farrell* (853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988)) made an excellent distinction between these two concepts. Judge Rich noted that “[a]ny invention that would in fact have been obvious under §103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?” (*Id.* at pages 1680-81). He went on to state that

The admonition that ‘obvious to try’ is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been ‘obvious to try’ would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. [*4 case cites omitted*]. In others, what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

(*Id.*, at 1681). The prior art cited by the Office Action clearly falls into Judge Rich’s second category. The Office Action states merely that the motivation to combine the references would have come from a desire to facilitate the study of disease. There is, however, no teaching in any of the cited references that suggests making the proposed combination to achieve the asserted

purpose of facilitating the study of disease. While it may prove to be a promising field of experimentation, the claimed method of determining the effect of an agent on a transgenic *Drosophila* comprising a neurodegenerative disease gene by digital image analysis is not taught or suggested by the prior art. The prior art gives no more than general guidance as to how one of skill in the art would carry out the claimed invention, and thus, fails to supply the required motivation to make the combination asserted by the Office Action. The suggested motivation to combine Brunner et al., Hendricks et al., and Chan, namely, to facilitate the study of disease in *Drosophila* is simply insufficient to support a finding of obviousness under §103.

In addition, whether taken alone or together, Brunner et al. and Hendricks et al. and Chan et al. fail to teach the generation of a phenoprint for a transgenic fly as recited in new claim 37.

Applicants accordingly request that the rejection be reconsidered and withdrawn.

**Rejection of Claims 23, 25-26, 29-31, and 34-35 Under §103(a)**

The Office Action states that claims 23, 25-26, 29-31, and 34-35 are rejected under §103 as being unpatentable over Bainton et al. in view of Hendricks et al. The Office Action states that Bainton et al. teach the method of claims 1-6, 9-12, and 15-17, but does not teach transgenic insects. The Office Action states that Hendricks et al. teaches transgenic *Drosophila* for studying sleep. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to modify the method Bainton et al. to use the transgenic *Drosophila* taught by Hendricks et al, “where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model.” Applicants respectfully disagree and traverse the rejection.

As stated above, to reach a *prima facie* finding of obviousness, the proposed combination of references must teach each aspect of the claimed invention. The instant claims (as amended) are each limited to methods that utilize transgenic *Drosophila* comprising a human neurodegenerative disease gene. Bainton et al. and Hendricks et al., whether considered alone or in combination, do not teach the claimed transgenic *Drosophila*. On this basis alone, the proposed combination of Bainton et al. and Hendricks et al. does not render the instant invention obvious.

In addition, whether taken alone or together, Bainton et al. and Hendricks et al. fail to teach the generation of a phenoprint for a transgenic fly as recited in new claim 37.

**Rejection of Claims 32-33 Under §103(a)**

The Office Action states that claims 32 and 33 are rejected under §103 as unpatentable in view of Bainton et al. and Hendricks et al., in view of Chan. The Office Action applies the combination of Bainton et al. and Hendricks et al. as described above, but notes that neither reference teaches a gene encoding a polypeptide with an expanded polyglutamine. The Office Action states that Chan discloses using transgenic *Drosophila* for elucidating the mechanisms of human neurodegenerative disease. The Office Action concludes that it would have been obvious to one of ordinary skill in the art to modify the methods of Bainton et al. and Hendricks et al. to use the *Drosophila* models taught by Chan, “where the motivation would have been to facilitate the genetic study of multiple mammalian diseases on a *Drosophila* model.” Applicants respectfully disagree and traverse the rejection. While the rejection is restricted to the polyglutamine repeat genes recited in claims 32-33, Applicants also address the rejection with respect to the human neurodegenerative disease gene limitation added to the claims by the instant amendments.

None of Bainton et al., Hendricks et al. or Chan provide the requisite motivation to make the combination suggested in the Office Action. Bainton et al. teaches a method for monitoring the behavior of *Drosophila* in response to psychostimulants (cocaine, nicotine, and ethanol). There is no teaching or even a suggestion in Bainton et al. to modify the described method of measuring behavioral responses to drugs of abuse to include a study of behavior and movement in *Drosophila* comprising a human neurodegenerative disease gene. Hendricks et al. merely teaches transgenic *Drosophila* that have mutations in the *timeless* or *period* genes, two genes involved in sleep and circadian rhythm and not even remotely associated with human neurodegenerative disease. The Chan reference is a review article that summarizes studies performed on various transgenic *Drosophila*. There is no teaching or suggestion in Chan to utilize transgenic *Drosophila* in concert with digital image analysis. The teachings of Chan are limited to genetic or molecular biological analysis of transgenic flies, and nowhere mentions monitoring behavior or movement. There is no motivation in Bainton et al. (focused on the

effects of drugs of abuse) or Hendricks et al. (not remotely concerned with human neurodegenerative disease) to combine their teachings with each other, or with Chan.

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). Upon reading Bainton et al., one of skill in the art may have been motivated to utilize the disclosed behavior analysis to study other drugs of abuse or potential therapeutics for drug abuse (since Bainton et al. concludes that the *Drosophila* model is a useful system to study the mechanisms underlying responses to multiple drugs of abuse), but would not have been motivated to extrapolate the teachings of Bainton et al. to study the effects of a test agent on a *Drosophila* comprising a human neurodegenerative disease gene. In addition, one of skill in the art would not have been motivated, upon reading the sleep studies of Hendricks et al., to extrapolate those teachings (focused on sleep) to the entirely different focus of study taught by Chan (focused on neurodegeneration). Upon reading the teachings of Chan, one of skill in the art would not have been motivated to completely modify the teachings of Chan, which utilized genetic and molecular biology analysis, to study flies by digital image analysis of behavior and movement. Lastly, upon reading Chan and/or Hendricks et al., one of skill in the art would not have been motivated to apply those teachings to the methods of Bainton et al., which are focused on the underlying mechanisms of drug abuse.

At best, the combination suggested by the Office Action would be obvious to try. The Federal Circuit has long held that “obvious to try” does not constitute “obviousness.” The court in *In re O’Farrell* (853 F.2d 894, 7 U.S.P.Q.2d 1673 (Fed. Cir. 1988)) made an excellent distinction between these two concepts. Judge Rich noted that “[a]ny invention that would in fact have been obvious under §103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?” (*Id.* at pages 1680-81). He went on to state that

The admonition that ‘obvious to try’ is not the standard under § 103 has been directed mainly at two kinds of error. In some cases, what would have been ‘obvious to try’ would have been to vary all parameters or try each of numerous

possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. [*4 case cites omitted*]. In others, what was ‘obvious to try’ was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

(*Id.*, at 1681). The prior art cited by the Office Action clearly falls into Judge Rich’s second category. The Office Action states merely that the motivation to combine the references would have come from a desire to facilitate the study of disease. There is, however, no teaching in any of the cited references that suggests making the proposed combination to achieve the asserted purpose of facilitating the study of disease. While it may prove to be a promising field of experimentation, the claimed method of determining the effect of an agent on a transgenic *Drosophila* comprising a human neurodegenerative disease gene by digital image analysis is not taught or suggested by the prior art. The prior art gives no more than general guidance as to how one of skill in the art would carry out the claimed invention, and thus, fails to supply the required motivation to make the combination asserted by the Office Action. The suggested motivation to combine Brunner et al., Hendricks et al., and Chan, namely, to facilitate the study of disease in *Drosophila* is simply insufficient to support a finding of obviousness under §103.

**Rejection of Claims 1-6, 9-12, 15-17, 21-24, 25-26, and 32-35 for Obviousness-Type Double Patenting**

The Office Action states that claims 1-6, 9-12, 15-17, 21-24, 25-26, 30 and 32-35 are rejected under the judicially created doctrine of obviousness-type double patenting in view of the claims of co-pending application serial number 10/676,424. Applicants hereby agree to file a terminal disclaimer to obviate the obviousness-type double patenting rejection upon notification of allowable subject matter in the instant case.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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